Exelixis Files IND Application for Novel Anticancer Compound XL820

April 25, 2005

SOUTH SAN FRANCISCO, Calif., April 25, 2005 /PRNewswire-FirstCall via COMTEX/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) for XL820. This novel small molecule anticancer compound potently inhibits receptor tyrosine kinases (RTKs) implicated in tumor proliferation and vascularization. XL820 is the fifth compound to advance in clinical development from Exelixis' internal drug discovery capabilities. Pending clearance by the FDA, Exelixis intends to initiate a Phase I clinical trial for XL820.

"I am very enthusiastic about the continued productivity of our R&D groups. We filed three INDs last year, and XL820 is the first of three anticipated INDs for this year. We believe these compounds are high quality and have the potential to provide substantial therapeutic benefit to patients in need," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "Before the end of 2005, we anticipate having eight compounds in clinical development, each of which potentially represents an important therapeutic advance."

XL820 inhibits the VEGF receptor, KIT and the PDGF receptor, which are clinically validated targets implicated in a variety of human cancers. XL820 exhibits dose-dependent growth inhibition in models of breast carcinoma, gliomas and leukemia. In an animal model of more advanced malignancy, significant tumor regression was seen. In non-clinical studies, XL820 has shown good oral bioavailability and sustained inhibition of target RTKs in vivo following a single oral dose.

Spectrum Selective Kinase Inhibitor(TM) (SSKI) Program

Exelixis' SSKI Program is focused on the development of compounds that are optimized to specifically target kinases implicated in tumor cell proliferation and angiogenesis thereby providing the potential for more potent therapeutic effects. The company currently has three compounds in active Phase I trials, which are XL647, XL999 and XL880, that came out of this program. Exelixis anticipates that it will complete the Phase I trials for XL647 and XL999 in the second half of 2005 and to initiate broad Phase II trial programs for these compounds as soon as practicable thereafter. The Phase I trial for XL880 was initiated in March and is actively enrolling patients. Exelixis is continuing to expand its SSKI Program by advancing additional diverse, high-quality compounds into clinical development, including XL844 and XL184 for which IND filings are anticipated in the first half of 2005, and has also made progress on earlier-stage compounds that are part of the SSKI Program.

About Exelixis

Exelixis, Inc. is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics across various disease areas. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline covers cancer and metabolism and is comprised of the following compounds: XL119 (becatecarin), for which a multinational Phase III clinical trial has been initiated in patients with bile duct tumors; XL784, initially an anticancer compound, which completed a Phase I clinical trial and is being advanced as a treatment for renal disease; XL647, XL999 and XL880, anticancer compounds currently in Phase I clinical trials; XL820 for which an IND has been filed; XL844 and XL184, potential IND candidates for the treatment of cancer; and multiple compounds in preclinical development for diseases including cancer and various metabolic and cardiovascular disorders. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies including GlaxoSmithKline (GSK) and Bristol-Myers Squibb Company. Pursuant to a product development and commercialization agreement between Exelixis and GSK, GSK has the option, after completion of Phase IIa clinical trials by Exelixis, to elect to develop a certain number of compounds in Exelixis' product pipeline, which may include the cancer compounds identified in this press release (other than XL119), thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis. For more information, please visit the company's web site at www.exelixis.com.

This press release contains forward-looking statements, including without limitation all statements related to Exelixis' clinical development program for XL820, the therapeutic and commercial potential of XL119, XL784, XL647, XL880, XL999, XL820, XL844 and XL184, other compounds in the Exelixis preclinical pipeline and its program in metabolic diseases. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "slated," "goal" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the ability of the company to successfully conduct the clinical trials for XL119, XL647, XL999, XL880, and XL820; the ability of the company to advance additional preclinical compounds into clinical development; the uncertainty of the FDA approval process; and the therapeutic and commercial value of the company's compounds. These and other risk factors are discussed under "Risk Factors" and elsewhere in our annual report on Form 10-K for the year ended December 31, 2004 and other filings with the Securities and Exchange Commission. Exelixis expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

SOURCE Exelixis, Inc.

Charles Butler, Associate Director, Corporate Communications of Exelixis,
+1-650-837-7277, or cbutler@exelixis.com